Notice of Allowability	Application No.	Applicant(s)	
	09/816,472	SMART ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *examiner's amendment of 6/7/2007*.

2. ☒ The allowed claim(s) is/are *11,48-50,58 and 72-108*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f)
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

107. (New) The device of claim 105 wherein the analyte fluid is transported from a location recessed from a portion of the penetration end forming any part of a tip.

108. (New): The device of claim 48, wherein the biosensor is in a cavity opening on a surface of one side of the substrate, the cavity extending into said one side on the microprobe portion near the body end or the body portion, the biosensor being an electrochemical biosensor or an optical biosensor configured to provide an electrical signal indicating change in analyte concentration, the device further comprising:

an interface structure and a signal carrier on or above the surface of said one side of the substrate, the signal carrier being a pair of electrically conductive leads configured to carry the signal from the biosensor to the interface structure, the interface structure being a pair of electrically conductive contacts; and

an open fluid channel formed in said one side of the substrate, the fluid channel opening along said surface of said one side from the penetration end to the biosensor, the open fluid channel being configured to transport analyte fluid to the biosensor by capillary action. --

The claims were amended to accept the indicated allowable subject matter and add dependent claims from the allowed claims.

The following changes to the drawings have been approved by the examiner and agreed upon by applicant: See attached drawing changes. In order to avoid abandonment of the application, applicant must make these above agreed upon drawing changes.

The following is an examiner's statement of reasons for allowance:

Claims 11, 48-50, 58, and 72-108 are allowable. Claims 11 and 72-101 defines over the art in that none of the art teaches the microfillet portion. In view of the discussion on page 12 of the specification, it is clear that the inclusion of such a portion is more than merely a change in shape and therefore defines over the art of record. Claims 48, 49, 58, and 102-108 define over the art in that none of the art shows the biosensor in a cavity on the substrate. Claim 50 defines over the art of record in that none of the art shows multiple biosensors on multiple sides of the substrate, as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
June 10, 2007

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Joshua Isenberg on June 7, 2007.

The application has been amended as follows:

In the specification:

On page 10, line 4, the word – biosensor –has been added before the word reagent.

On page 11, line 4, after the word micrometers, the follows has been added; -- excluding the width of the microfillet portion --.

On page 11, lines 4-5, the phrase "(of about 30 micrometers)" has been deleted.

On page 12, line 17, the word "16p" has been deleted.

On page 14, line 22, the word "optrode" has been changed to – optical --.

On page 14, line 23, the word "optrode" has been changed to – optical signal carrier --.

These changes were merely made to clarify the record.

In the claims:

The claims have been rewritten as follows: --

Claims 1-10. (cancelled).

11. (Currently amended): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, the microprobe device comprising:

a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having ~~an~~ front side and a back side extending in the X and Y dimensions;

a body portion formed by the silicon substrate; a microprobe portion formed by the silicon substrate, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluids; and

a biosensor integrated into the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence; and

a silicon microfillet portion at the connection between the body end of the microprobe portion and the body portion.

Claims 12-47. (cancelled).

Claim 48. (Previously presented): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:

a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having a front side and a back extending in the X and Y dimensions and a cavity extending into the silicon substrate in the Z thickness dimension

a body portion formed by the silicon substrate;

a microprobe portion formed by the silicon substrate, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluids; and

a biosensor integrated into the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence, the biosensor being deposited onto the silicon within the cavity.

49. (Previously presented): The microprobe device of claim 48, wherein the cavity extends completely through the substrate in the Z thickness dimension.

50. (Currently amended): A microprobe device for providing a signal to an external analyte meter indicating analyte presence in an analyte-containing bodily fluid of a subject, comprising:

a silicon substrate having an X length dimension and a Y width dimension and a Z thickness dimension, and having a front side and a back side extending in the X and Y dimensions;

a body portion formed by the silicon substrate;

a microprobe portion formed by the silicon substrate, having a body end connected to the body portion, and having a penetration end extending away from the body portion in the X length dimension for penetrating into the subject to access the fluids; and

at least one biosensor integrated into each side of the silicon substrate, for sensing analyte presence and for providing a signal in response to the analyte presence.

Claims 51-57. (cancelled).

58. (Currently amended): The microprobe device of claim 48, wherein the silicon substrate is single crystal silicon.

Claims 59-71. (cancelled).

72. (New): The device of claim 11, wherein the biosensor is an optical biosensor, an electrochemical biosensor, an electrogravimetric biosensor or a thermal biosensor.

73. (New): The device of claim 72, further comprising a signal interface structure coupled to the biosensor.

74. (New): The device of claim 72, wherein the signal is an electrical output signal, the device further comprising: a signal interface structure and a signal carrier; wherein the signal carrier includes one or more electrically conductive leads; the signal interface structure includes one or more electrically conductive contacts.

75. (New): The device of claim 74, wherein the interface structure is located on the surface of the body portion of the substrate, the body portion being configured to provide an electrical contact and sliding mechanical connection with an analyte meter.

76. (New): The device of claim 11, wherein the substrate has a front surface, the biosensor is an optical biosensor or an electrochemical biosensor positioned at a location on the front surface of the body portion, the device further comprising:

an open fluid channel formed in said substrate, the fluid channel opening along said front surface from the penetration end of the microprobe portion to the location on the body portion where the biosensor is positioned for sensing analyte presence, said open fluid channel being configured to transport the analyte-containing bodily fluid to said location by capillary action.

77. (New): The device of claim 76, wherein the open fluid channel is uncovered over the entire length of the microprobe portion.

78. (New): The device of claim 76, wherein the penetration end terminates in a point configured to make an incision in skin, the open fluid channel being configured to transport the analyte-containing bodily fluid from the incision to the

location on the body portion where the biosensor is positioned for sensing analyte presence.

79. (New): The device of claim 11, wherein the substrate has a front surface, the biosensor is an optical biosensor or an electrochemical biosensor positioned at a location on the front surface of the body portion, the device further comprising:

an open fluid channel formed in said substrate, the fluid channel opening along said front surface from the penetration end of the microprobe portion to the location on the body portion where the biosensor is positioned for sensing analyte presence, said open fluid channel being configured to transport the analyte-containing bodily fluid to said location by capillary action; and

a cover over the body portion of the substrate; the cover being adapted to engage a base to close said cover.

80. (New): The device of claim 11, wherein the biosensor is on a surface on one side of the substrate, the biosensor being positioned on top of the surface on the body portion of the substrate, or on top of the surface on the microprobe portion near the body end, the device further comprising:

one or more open fluid channels, each fluid channel formed in said one side of the substrate, each of the one or more fluid channels opening along the surface of said one side from the penetration end to the biosensor, each of said one or more open fluid channels being configured to transport analyte fluid to the biosensor by capillary action.

81. (New): The device of claim 80, wherein each of the one or more open fluid channels is uncovered over any portion that passes into the subject during penetration.

82. (New): The device of claim 80, wherein each of the one or more open fluid channels opens along the surface of said one side from a tip of the penetration end to the biosensor

83. (New): The device of claim 80, wherein each of the one or more open fluid channels opens along the surface of said one side from a location at the penetration end recessed behind any area of tip formation to the biosensor

84. (New): The device of claim 80, wherein each of the one or more open fluid channels has a V-groove cross-section.

85. (New): The device of claim 80, wherein each of the one or more open fluid channels has a cross-section of any shape produced by plasma etching.

86. (New): The device of claim 80, wherein the surface on the body portion of the substrate is planar.

87. (New): The device of claim 80, further comprising a cavity wherein the biosensor is configured to be positioned over the cavity or over the open fluid channel.

88. (New): The device of claim 11, wherein any biosensor is located sufficiently back along the microprobe portion towards the body end that it does not come into contact with any part of the penetration end so as not to affect the sharpness of a point of the penetration end or interfere with penetration of the microprobe portion into the subject.

89 (New): The device of claim 11, wherein the microprobe portion is width tapered along the entire the X length dimension, converging continuously from a larger Y width dimension at the body end to a smaller Y width dimension at the termination of the penetration end, wherein the rate of convergence of the microprobe taper is non-uniform for optimizing stress distribution during penetration.

90. (New): The device of claim 11, wherein the X length of the microprobe portion is from about 0.5 mm to about 2.5 mm, and the penetration depth of the microprobe portion is from about 0.5 mm to about 2 mm.

91. (New): The device of claim 11, wherein the X length of the body portion is from about 0.3 mm to about 2 mm, and the Y width of the body portion is from about 0.3 mm to about 2 mm.

92. (New): The device of claim 11, wherein the Y width dimension of the microprobe portion terminates in a symmetrically shaped point at the penetration end.

93. (New): The device of claim 11, wherein the Y width dimension of the microprobe portion terminates in a chisel shaped point at the penetration end.

94. (New): The device of claim 11, wherein the penetration end of the microprobe portion is thinner than the body portion.

95. (New): The device of claim 11, further comprising multiple biosensors integrated into one side of the silicon substrate, wherein any subset of the multiple biosensors is located on the body portion or on the microprobe portion near the body end, and wherein the device further comprises one or more open fluid channels in the substrate for each biosensor in the subset

96. (New): The device of claim 50 wherein any subset of the multiple biosensors is located on the body portion or on the microprobe portion near the body end, and wherein the device further comprises one or more open fluid channels in the substrate for each biosensor in the subset.

97. (New): The device of claim 11, further comprising: a base through the center of which the microprobe device is mounted, the base having a bottom face generally normal to said microprobe portion and a stabilizing surface applied to the bottom face.

98. (New): The device of claim 97, further comprising: a cover over the body portion of the substrate, the cover engaging the base for closing said cover; and a signal transmitter configured to receive a sensed signal from the biosensor and configured to provide a transmitted electrical signal; the signal transmitter

including a source of electrical power and a signal conversion capability, said signal transmitter being located on the body portion of the substrate, the base or the cover.

99. (New): The device of claim 97, wherein the biosensor is on the body portion of the substrate, the device further comprising: an open fluid channel formed in the substrate, the fluid channel opening longitudinally along a surface of the substrate from the penetration end to the biosensor, said open fluid channel being configured to transport analyte fluid to the biosensor by capillary action.

100. (New): The device of claim 11, further comprising a cover over the body portion of the substrate; the cover being adapted to engage a base to enclose said body portion.

101. (New): The device of claim 11, further comprising a layer on the substrate, wherein the biosensor is deposited on the layer, the layer being an electrically insulative layer.

102. (New): The device of claim 48, wherein the cavity is configured to vary in all three dimensions to accommodate the size of the biosensor.

103. (New): The device of claim 48, further comprising: a signal interface structure and a signal carrier; wherein the biosensor is an optical biosensor responsive to the analyte presence by alterations in photon energy of the signal, the signal carrier is a photon containment structure and the interface structure is an optical coupler for interfacing with a detector.

104. (New): The device of claim 49, wherein the biosensor is in the cavity and the cavity is located on the microprobe portion near the body end or the body portion; the device further comprising:

an open fluid channel formed in one side of the substrate, the fluid channel opening along the surface of said one side from the penetration end to

the biosensor, the open fluid channel being configured to transport analyte fluid to the biosensor by capillary action.

105. (New): The device of claim 48, wherein the biosensor is integrated into a surface of a cavity opening on a surface of one side of the substrate, the cavity extending into said one side on the microprobe portion near the body end or the body portion; the device further comprising:

an open fluid channel formed in said one side of the substrate, the fluid channel opening along the surface of said one side from the penetration end to the biosensor, the open fluid channel being configured to transport analyte fluid to the biosensor by capillary action.

106. (New) The device of claim 105 wherein the open fluid channel is configured to transport analyte fluid to the biosensor by capillary action without a cover over any portion of the channel that passes into the subject during penetration.